REMARKS

Claims 12, 15, 32, 52, 54-56, 58 and 59 are pending. Claims 13, 14 and 53 have been cancelled in prior Replies. Claims 1-11, 16-31, 33-51 and 57 have been withdrawn from consideration due to the Examiner's restriction requirement. These claims have been cancelled or withdrawn from consideration without prejudice to, or disclaimer of, the subject matter thereof. Applicant reserves the right to file continuation applications directed to the subject matter of any cancelled or withdrawn claim for any reason.

The present amendments to claims 12, 52, 58 and 59 place the application in better condition for examination. It is submitted that no new matter has been introduced by the present amendments, and entry of the same is respectfully requested. By these amendments, Applicant does not acquiesce to the propriety of any of the Examiner's prior rejections and does not disclaim any subject matter to which Applicant is entitled. *Cf. Warner Jenkinson Co. v. Hilton-Davis Chem. Co.*, 41 U.S.P.Q.2d 1865 (U.S. 1997).

I. Rejection of Claims 12, 15, 32, 52, 54-56, 58 and 59 Under 35 U.S.C. § 102(b)

The Examiner rejected claims 12, 15, 32, 52, 54-56, 58 and 59 under 35 U.S.C. § 102(b) as anticipated by *Perrin-Cocon et al.*, Biochem. J. (1999) 338: 123-130; U2 on form PTO-892 ("*Perrin-Cocon et al.*"). Office Action mailed 1 June 2005 ("OA"), page 2. Applicant respectfully traverses.

In order to support an anticipation rejection under 35 U.S.C. § 102(b), the Examiner must show that each and every element of the claimed invention is shown identically in a single reference. *In re Bond*, 15 U.S.P.Q.2d 1566, 1567 (Fed. Cir. 1990) citing *Diversitech Corp v. Century Steps, Inc.*, 7 U.S.P.Q.2d 1315, 1317 (Fed. Cir. 1988). As explained below, *Perrin-Cocon et al.*, is not prior art under 35 U.S.C. § 102(b). *Perrin-Cocon et al.*, also does not contain each and every element of the claimed invention as they presently appear. Therefore, the invention as presently claimed is novel and inventive over the prior art of record and the present rejection should be reconsidered and withdrawn.

First, *Perrin-Cocon et al.*, does not anticipate claims 12, 15, 32, 52, 54-56, 58 and 59 of the 09/831,112 application because *Perrin-Cocon et al.*, was published after the priority date of

the 09/831,112 application. Specifically, *Perrin-Cocon et al.*, was published in 1999 while the 09/831,112 application claims priority back to 05 November 1998 based on FR9813946. Therefore, this reference is not prior art and cannot anticipate the claims of the 09/831,112 application. As a result, the Examiner's rejection of claims 12, 15, 32, 52, 54-56, 58 and 59 should be withdrawn.

Even if *Perrin-Cocon et al.*, was prior art, it still would not anticipate claims 12, 15, 32, 52, 54-56, 58 and 59. As will be explained more fully below, the present rejections are premised on the incorrect assumption that vesicles derived from different eukaryotic cell types are not distinct from one another.

In rejecting the claims of the present invention, the Examiner asserts that *Perrin-Cocon et al.*, teaches "isolation of intracellular compartments involved in antigen processing from B cells"; "isolation of vesicles containing MHC class II molecules"; and that "isolated vesicles display no morphological differences from classical endocytic vesicles." OA, page 2. While the Examiner acknowledges that *Perrin-Cocon et al.*, does not teach isolated vesicles derived from mastocytes, the Examiner does not view these vesicles as different from vesicles derived from other eukaryotic cell types. *Id.* at 2-3. Further, the Examiner suggests that while the present claims are drawn to vesicles comprising *recombinant* MHC class II molecules and *Perrin-Cocon et al.*, contemplates *natural* MHC class II molecules, that "there is no structural difference between ... natural ... and ... recombinant MHC class II ...." *Id.* at 3. Finally, the Examiner suggests that the instant claims are product claims drawn to the end product of an isolated vesicle and that this end product is not distinct from isolated vesicles produced by other eukaryotic cells. *Id.*

In response to the Examiner's assertions, the Applicant points out that *Perrin-Cocon et al.*, relates to a method for purifying intracellular compartments from human macrophage-like cells (activated U937 cells) and B lymphocytes. Page 123, 2nd column. While the Examiner assumes that vesicles derived from all eukaryotic cell types are equivalent (and it is true that such vesicles can be *morphologically* similar), vesicles that derive from U937 macrophages and B lymphocytes are quite different from mastocyte-secreted vesicles. This difference is especially apparent in the vesicles' differing structures, brought about by different protein and lipid compositions within the vesicle. Importantly, the differences in protein and lipid composition is

highly dependent on the cell type from which the vesicle originates. This assertion is supported by *Thery et al.*, Nature Reviews (August 2002) 2: 569-579 which provides: "[m]ore extensive analyses involving trypsin digestion and mass spectrometry to identify unknown or unexpected cellular proteins that are present in exosomes have been carried out also on exosomes derived from DCs, mast cells, and intestinal epithelial cells (enterocytes)"; ".[b]oth ubiquitous and cell-specific proteins might be targeted selectively to exosomes..."; and [e]xosomes contain a series of cell-specific transmembrane proteins including α- and β- chains of integrins (such as αM and DCs, β2 on DCs and T cells and α4 β1 on reticulocytes)." Page 570, 2nd column; page 571, 2nd column.

As stated above, in addition to various protein compositions, exosomes also show different lipid compositions. For instance, *Thery et al.*, also teaches that, "[t]he presence of lyso-bis-phosphatidic acid, a lipid that is enriched in late endocytic compartments, has been reported in B-cell derived exosomes. Phosphatidylserine (PS) - a lipid that is present normally at the cytosolic side of the plasma membrane – is also present, but at low levels at the surface of exosomes that are derived from platelets and DCs .... The lipid composition of exosomes from other cell types is not known yet. Page 571, 2nd column.

Based on the fundamental differences in protein and lipid compositions described in the preceding paragraphs, it should be clear that mastocyte-derived vesicles are distinct from the macrophage or B-cell derived vesicles of *Perrin-Cocon et al.*. Thus, even if *Perrin-Cocon et al.*, relates to "isolation of intracellular compartments involved in antigen processing from B cells"; and "isolation of vesicles containing MHC class II molecules"; and suggests that "isolated vesicles display no morphological differences from classical endocytic vesicles," this does not anticipate mastocyte-derived vesicles with distinct protein and lipid compositions, as claimed. As a result, this reference does not teach or suggest each and every element of the claimed inventions, and claims 12, 15, 32, 52, 54-56, 58 and 59 are not anticipated by it.

In rejecting claims 12, 15, 32, 52, 54-56, 58 and 59 under 35 U.S.C. § 102(b) as anticipated by *Perrin-Cocon et al.*, the Examiner also suggested that there is "no structural difference between the natural MHC class II molecules taught by *Perrin-Cocon et al.*, and the recombinant MHC class II presently recited in the claims." OA, page 3. The Applicant contends that one skilled in the art would readily understand that the recombinant MHC class II molecules

recited in the claims do not refer to endogenous MHC class II proteins. Nonetheless, and without acquiescing to the propriety of the Examiner's position, the Applicants have amended claims 12, 58 and 59 to recite "heterologous recombinant class II molecules," as supported by, for example, page 12, lines 19-22 of the Specification. The term "heterologous" means the protein is not present in the same form in the exosomes of the invention as in their natural state (see Specification page 12, last line - page 13, lines 1-2).

Based on the foregoing, Applicant respectfully submits that *Perrin-Cocon et al.*, is not prior art under 35 U.S.C. § 102(b) and does not teach or suggest isolated membrane vesicles secreted from mastocyte or mastocyte-derived cells comprising heterologous recombinant class II molecules of the major histocompatibility complex. Thus, *Perrin-Cocon et al.*, does not teach each and every element of the claimed invention identically and does not anticipate the claims of the present application.

Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of claims 12, 15, 32, 52, 54-56, 58 and 59 under 35 U.S.C. § 102(b).

CONCLUSION

Applicant has properly and fully addressed the Examiner's grounds for rejection. Applicant submits that the present application is now in condition for allowance. If the Examiner has any questions or believes further discussion will aid examination and advance prosecution of the application, a telephone call to the undersigned is invited.

If there are any further fees due in connection with the filing of the present reply, please charge the fees to undersigned's Deposit Account No. 50-1067. If a fee is required for an extension of time not accounted for, such an extension is requested and the fee should be charged to undersigned's deposit account.

Respectfully submitted,

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